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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 18

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Filing Date: 09/07/90
Appellant(s): Jose Calatayud, et al.

93-3515

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BOARD OF PATENT APPEALS
AND INTERFERENCES

John C. Tiernan
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed
2/19/93.

(1) *Status of claims.*

The statement of the status of claims contained in the brief
is correct.

(2) *Status of Amendments After Final.*

The appellant's statement of the status of amendments after
final rejection contained in the brief is correct.

(3) *Summary of invention.*

The summary of invention contained in the brief is correct.

(4) *Issues.*

The appellant's statement of the issues in the brief is
correct.

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The examiner agrees with the statement of issues on appeal with the caveat that the statement is rather slanted. A more succinct statement would be: "Are the instantly claimed compounds and compositions obvious within the meaning of 35 USC 103 over structurally similar compounds which share the same utility?"

(5) *Grouping of claims.*

The rejection of claims 1-3, 14, 15 and 17-20 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together. See 37 C.F.R. § 1.192(c)(5).

(6) *Claims appealed.*

A substantially correct copy of appealed claim 1 appears on page 1 of the Appendix to the appellant's brief. The minor errors are as follows: in the definition of R_2 , the formulas should be $\overset{\text{O}}{\parallel}\text{-C-CH}_3$, and $\overset{\text{O}}{\parallel}\text{-C-CH-CH}_3$.

(7) *Prior Art of record.*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

3,983,233	BRATTSAND et al.	9-1976
3,992,534	BRATTSAND et al.	11-1976

(8) *New prior art.*

No new prior art has been applied in this examiner's answer.

(9) *Grounds of rejection.*

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The following ground(s) of rejection are applicable to the appealed claims.

Claims 1 and 17-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Brattsand, US 3,983,233 (Brattsand A).

The claimed compounds and compositions embrace compounds of the formula I set forth in Appendix A, below. Brattsand A teaches compounds of formula II set forth in Appendix A below, as well as species Ex. 22 and 24 set forth in Appendix A below.

The differences between the instantly claimed compounds and compositions and those of Brattsand A are apparent from the formulas in Appendix A, below.

From formulas I and II below, it is apparent that the instantly claimed compounds and compositions are generically embraced by the compounds of Brattsand; i.e. when in formula I, (instant claims) $R_2 = -\overset{\text{O}}{\underset{\text{||}}{\text{C}}}\text{CH}_3$ and $R_1 = -\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_3$, $-\overset{\text{CH}_3}{\underset{\text{||}}{\text{C}}}-\text{CH}_3$ or $\overset{\text{CH}_3}{\underset{\text{||}}{\text{C}}}-\text{CH}_2\text{CH}_3$ and X_1, X_2 may be H or F, the compounds are embraced by formula II (Brattsand A) $Z = \overset{\text{O}}{\underset{\text{||}}{\text{C}}}\text{AK}$, $\text{AK} = \text{C}_1\text{-C}_{12}$ alkyl and $\text{R} = \text{straight or branched hydrocarbon of 2-10 carbons}$.

Moreover, Brattsand teaches examples 22 and 24 which differ from the instantly claimed compounds and compositions in only one position, i.e. the alkyl corresponding to R_1 on formula I (instant claims) and R in formula II (Brattsand (A)).

As may be seen, examples 22 and 24 are the next adjacent homologs of the instantly claimed compounds and compositions wherein R_1 is butyl. See Appendix B, below for comparison of Brattsand A, Ex. 22 and 24, and instant claims wherein R_1 =butyl.

In short, Brattsand A specifically teaches the next higher and lower adjacent homologs to the instantly claimed compounds and compositions and generically teaches the equivalence of branched and unbranched alkyl at the analogous position. One of ordinary skill in the art would have modified the instantly claimed compounds and compositions to arrive at the instantly claimed homologs and isomers because they are so structurally similar that they would have been expected to have very similar properties as anti-inflammatory agents.

In re Henze, 85 USPQ 261. In re Payne, 203 USPQ 245. In re Hass, 60 USPQ 544. In re Hass, 60 USPQ 548.

Claims 1-3 and 17-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Brattsand (A) in view of Brattsand et al., US 3,992,534 (Brattsand B).

Brattsand A teaches compounds and compositions as explained above. The sole remaining limitation not discussed above is specifically claimed in claims 2 and 3, drawn to particular epimers (stereoisomers) of the racemic parent compound. This limitation is optional in claims 1 and 17-20. Thus, Brattsand A is deficient only in that it fails to motivate one of ordinary

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skill in steroidal anti-inflammatory art to separate epimers for use in anti-inflammatories.

Brattsand B alleviates this deficiency. Brattsand B teaches, at col. 2, first full paragraph that "[t]he separation process according to the present invention has made it possible to investigate the physiological characteristics of the separated stereoisomers" (i.e. epimers). Further, it was found that one stereoisomer (epimer) is more active biologically than the racemic mixture and the complimentary stereoisomer. It is the examiner's position that this is ample motivation to isolate the epimers (stereoisomers) claimed in claims 2 and 3, especially since the compounds of Brattsand A and Brattsand B have the same utility and are structurally very similar.

One of ordinary skill in the art would have modified the compounds and compositions of Brattsand A in accordance with the separation procedure of Brattsand B to arrive at the instantly claimed compounds, compositions and methods of use because they are so structurally similar that one of ordinary skill in the art would have expected them to have very similar properties. In re Payne, supra. In re Henze, supra. In re Hass, supra. In re Adamson & Duffin, 125 USPQ 233. Brenner v. Ladd 147 USPQ 87.

(10) *New ground of rejection.*

This Examiner's Answer does not contain any new ground of rejection.

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(11) *Response to argument.*

Applicants arguments may be characterized as being two fold:

- 1) The examiner has failed to make out a prima facie case of obviousness and
- 2) Assuming arguendo that a prima facie case has been made out, the data presented would tend to provide sufficient evidence of unexpected properties that the instantly claimed compounds, compositions and methods of use would not have been obvious at the time the invention was made.

Examiner's Answers to Appellant's Arguments:

- 1) Contrary to appellants arguments, a strong prima facie case of obviousness within the meaning of 35 USC 103 has been made out. Appellants claims are drawn to homologs (examples 22 and 24 of Brattsand A are the next higher and lower adjacent homologs of instantly claimed compounds wherein R_1 is $\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_3$) and isomers (example 22 is a positional isomer of the instantly claimed compounds wherein R_1 is $\overset{\text{CH}_3}{\text{CH}}-\text{CH}_3$ and example 24 is a positional isomer of instantly claimed compounds wherein R_1 is $\overset{\text{CH}_3}{\text{CH}}-\text{CH}_2\text{CH}_3$). Appellants' arguments (see pages 7 and 8 of the Brief) that the activity of closely structurally related compounds is unpredictable is not persuasive. True, one of ordinary skill in the art would expect there to be some variation, even wide variation in the activity of structurally related compounds from a reading of Brattsand A. However, one of

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ordinary skill in the art would still reasonably expect closely related chemical structures to possess similar properties.

Appellants have not refuted this expectation. In fact, at page 5 of the brief. Appellants argue that "the goal in the development of new corticoids with anti-inflammatory activity of therapeutic utility, will be to obtain a better quantitative response.

(emphasis in original). Appellants have not demonstrated a better quantitative response as is discussed below.

2) To the end of supporting the allegation that better quantitative results are gotten with the instantly claimed compounds, appellants come with data, newly presented in the Brief. These data have not been considered because

a) they are not in declaration form and therefore are not competent, and

b) appellants have not shown good and sufficient reasons why the data was not earlier presented.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Muhammad J. Shah

ADVISORY PATENT EXAMINER
GROUP 120 - ART UNIT 122

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Serial No. 07/578,942

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew V. Grumbling whose telephone number is (703) 308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

ms

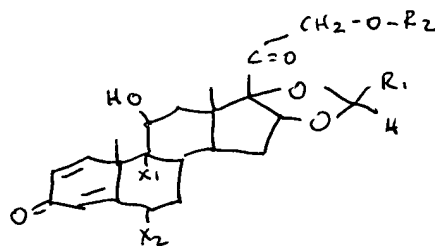
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April 2, 1993
April 13, 1993

Murkund J. Shah

LEWIS J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 120 - ART UNIT 122

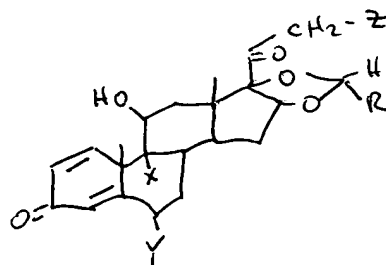
Appendix A

Formula I (Instant claims)



$X_1, X_2 = \text{H or F}, R_2 = \text{C}(=\text{O})\text{CH}_3, \text{C}(=\text{O})\text{CH}(\text{CH}_3)\text{CH}_3,$
 $R_1 = \text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_3, \text{CH}(\text{CH}_3)\text{CH}_3, \text{CH}(\text{CH}_3)\text{CH}_2\text{CH}_3$

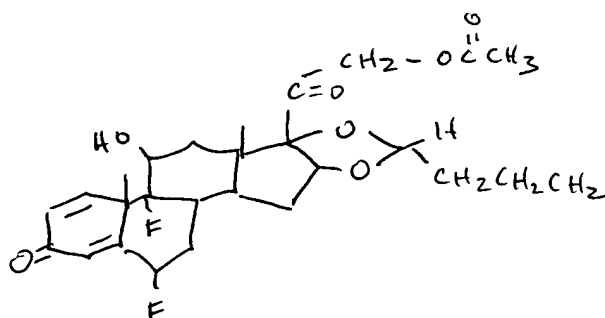
Formula II (Brattsand A)



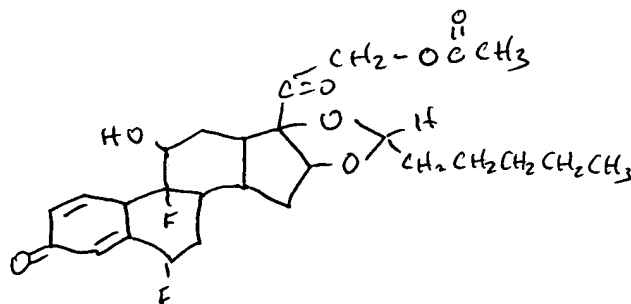
$X, Y = \text{H/F}, Z = \text{OH}, \text{OCH} \text{ or } \text{OC}(\text{CH}_2)_{0-10}\text{-CH}_3$

R is straight or branched hydrocarbon of 2-10 carbons.

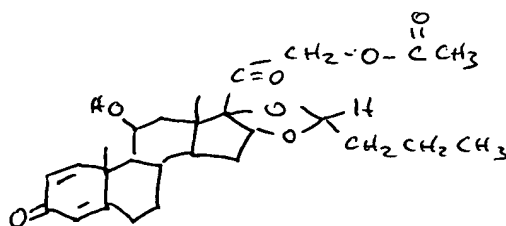
Ex. 22 (Brattsand A)



Ex. 24 (Brattsand A)

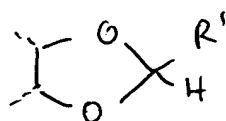


Ex. 16
(Brattsand A)



Appendix B

Formula I
(Instant claims)

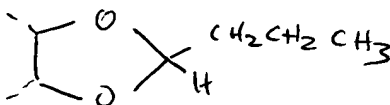


$R_1 = -CH_2CH_2CH_2CH_3,$

$-CH(CH_3)-CH_3,$

$-CH(CH_3)CH_2CH_3;$

Ex. 22 (Dioxolo ring only)
(Brattsand A)



Ex. 24 (Dioxolo ring only)
(Brattsand A)

